REMARKS

In the Office Action dated December 10, 2008, the Examiner states that this application contains the following groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I. Claims 1-12, drawn to a method for preventing onset of an autoimmune disease in a subject comprising administering Flt-3L.

Group II. Claims 13-27, drawn to a method for modulating immune tolerance against cancer or pathogenic agent in a subject comprising administering Flt-3L.

In order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group I, claims 1-12, drawn to a method for preventing the onset of an autoimmune disease in a subject comprising administering Flt-3L. However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

Applicants respectfully submit that a requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression 'technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

The Examiner states that Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Specifically, the Examiner contends that the two groups represent multiple methods; therefore pursuant to 37 C.F.R. §1.475(a)-(d), the application contains claims drawn to more than one categories of invention and cannot be considered to have unity of invention.

Applicants respectfully submit that the methods of Groups I and II share the feature that an Flt-3 ligand is being administered, which selectively elevates particular subtypes of dendritic cells thereby facilitating the maintenance of a tolerogenic state in a subject and enhancing an immune response. See also page 4, lines 8-20 of the specification. Therefore, Groups I and II are linked together by a single inventive concept.

The Examiner refers to Maliszewski et al., Pathol. Biol. (2001), 49: 481-483, which allegedly teaches administration of an Flt-3 ligand *in vivo* to expand dendritic cells to treat cancer, infectious diseases, autoimmunity, among others. The Examiner is of the opinion that the features of claims 1 and 12 are disclosed in this reference, and therefore the present claims do not present any special technical feature.

Applicants respectfully submit that unity of invention is the issue at hand. The Examiner should not rely on an evaluation regarding novelty and/or inventive step of the present invention over certain prior art in order to determine whether the requirement of unity of invention is satisfied under PCT Rule 13.1. Applicants should be given the opportunity to argue on the merits during prosecution whether the claims are novel and unobvious over a cited prior art. Restriction of the claims at this stage would deny Applicants such an opportunity.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of the two groups, one from the other, as presented by the Examiner.

It is respectfully submitted that Claims 1-27 satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the pending claims.

Respectfully submitted,

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